

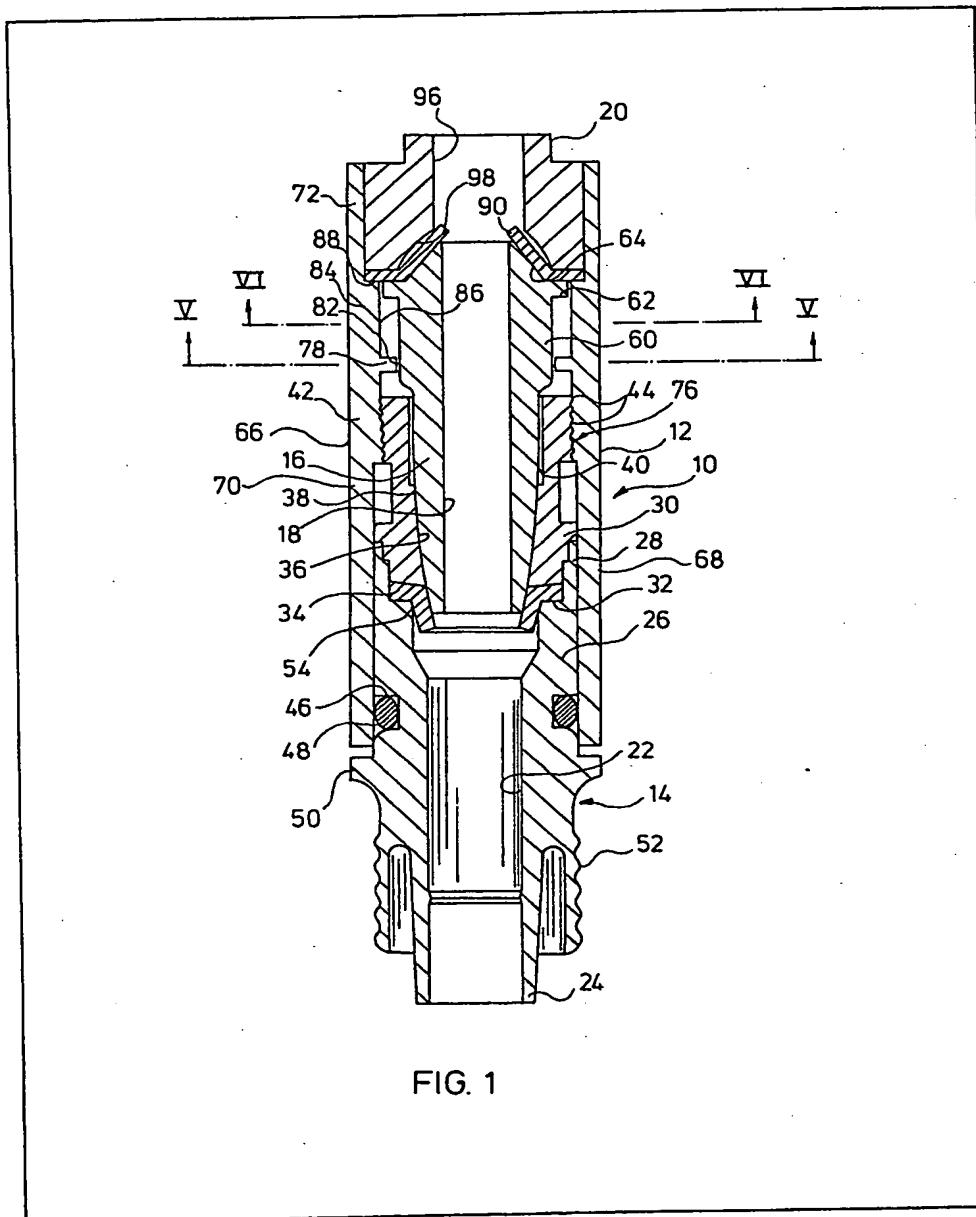
(12) UK Patent Application (19) GB (11) 2 118 440 A

(21) Application No 8306505
(22) Date of filing 9 Mar 1983
(30) Priority data
(31) 3210148
(32) 19 Mar 1982
(33) Fed. Rep of Germany (DE)
(43) Application published
2 Nov 1983
(51) INT CL⁹
A61M 5/31
(52) Domestic classification
A5R GE
(56) Documents cited
DE 3100622
DE A 2817102
(58) Field of search
A5R
(71) Applicants
Fresenius AG,
(FR Germany),
Gluckensteinerweg 5,
D-6380 Bad Homburg,
Federal Republic of
Germany.
(72) Inventors
Dr. Bernd Mathieu
(74) Agent and/or Address for
Service
Bailey Walsh and Co.,
5 York Place,
Leeds LS1 2SD.

(54) A self-sealing connector

(57) A self-sealing tubing connector for medical apparatus has two valve disks, 34,90, for sealing it in the uncoupled condition of the connector. Each valve disk has slits or other openings normally kept shut by the elasticity of the material. There is one such disk in the male part and one in the female part 14. The male element 12 is in the form of a

sliding central tube 60. When the connector is coupled up, the slits in the valve disk in the female part are opened by the central tube, which at one end has a male LUER cone face 38 for use with a female or inner cone face 36 in the female connector part. The central tube is pushed back axially and the disk in the male part is opened up. A force or wedging fit is produced between the male and female cone faces of the connector so that the connector parts are locked together.



GB 2 118 440 A

2118440

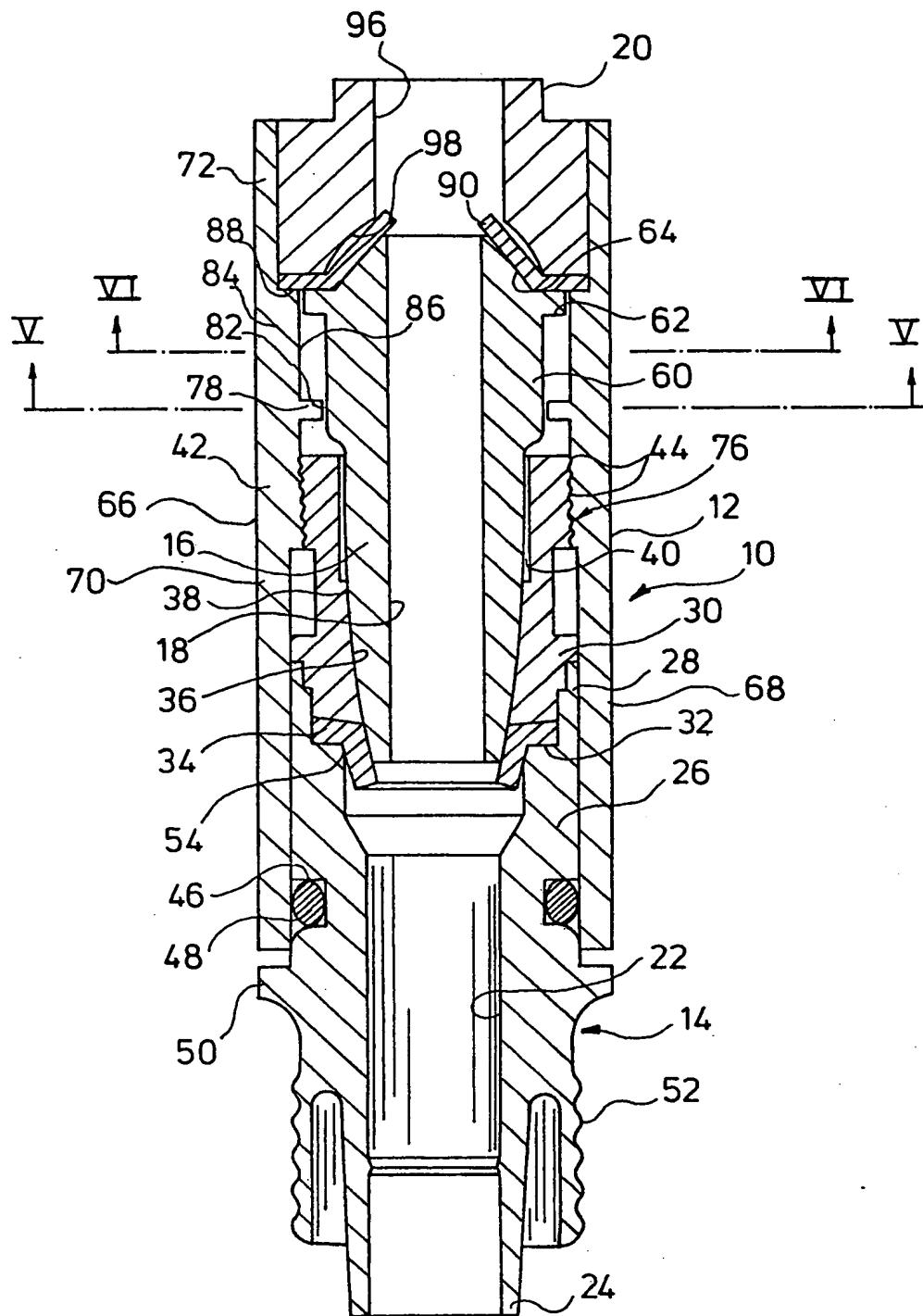
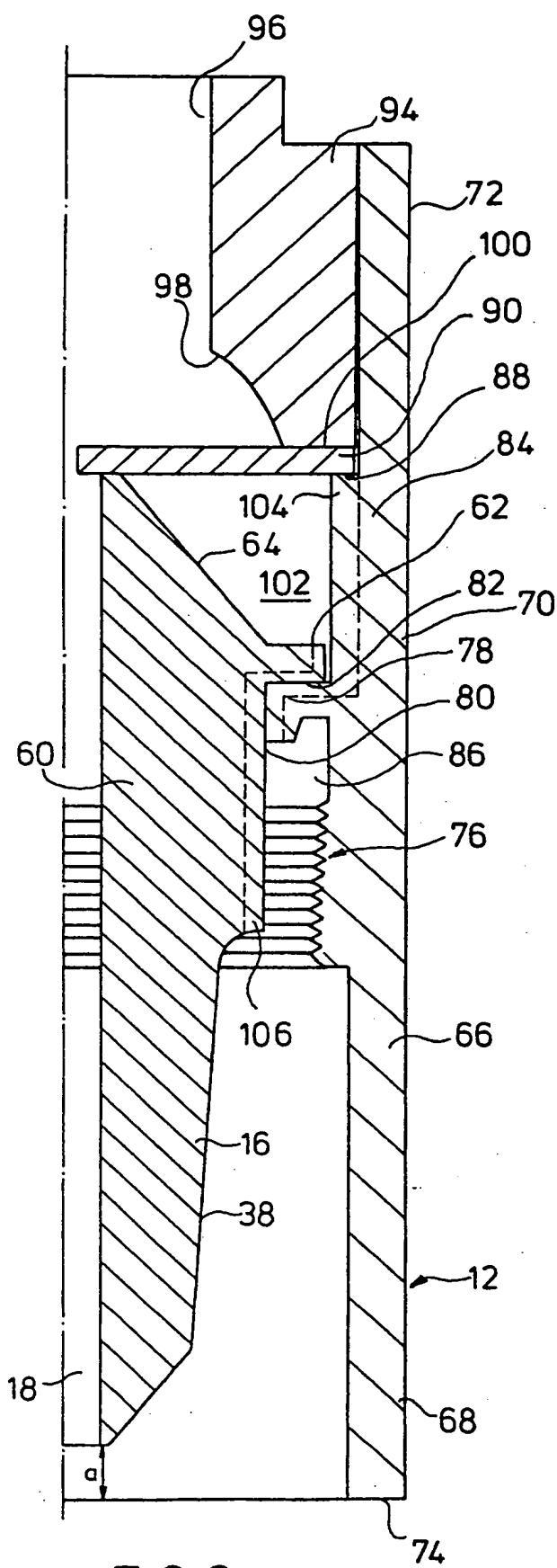
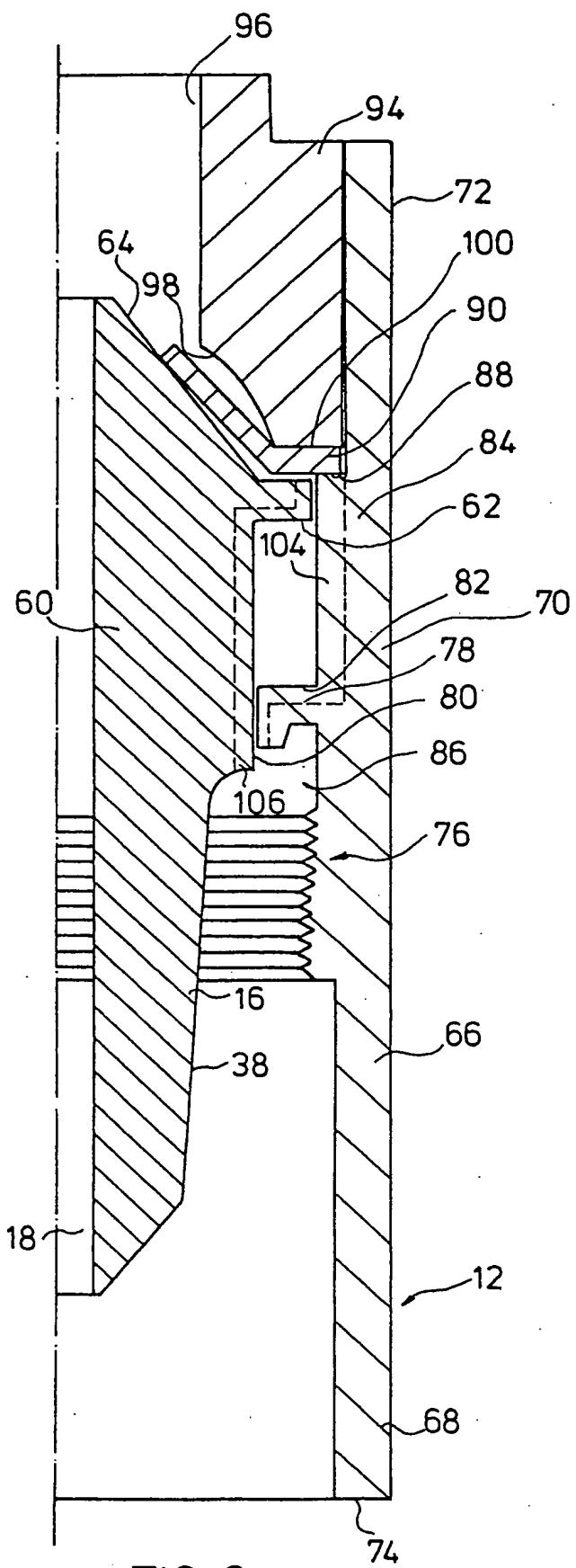
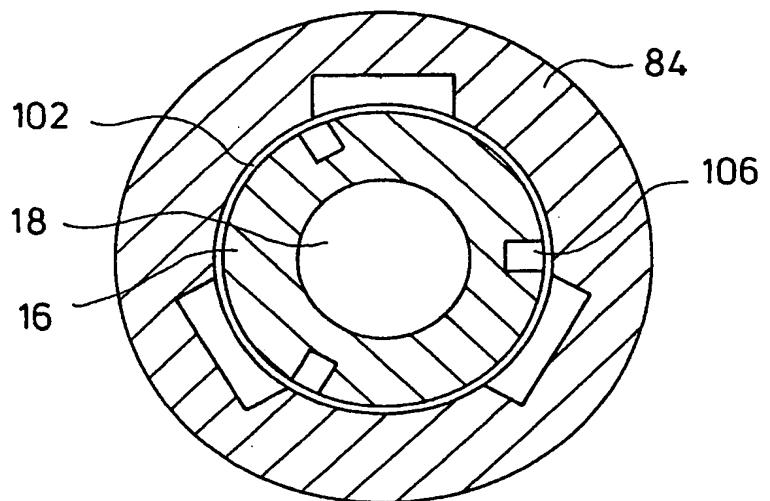
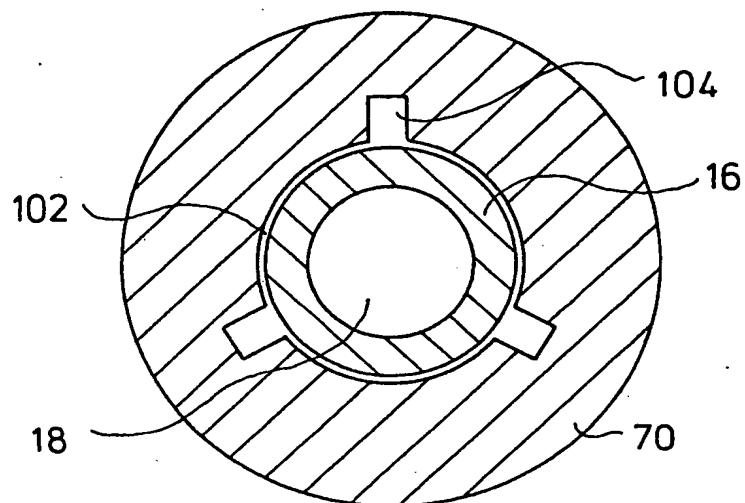
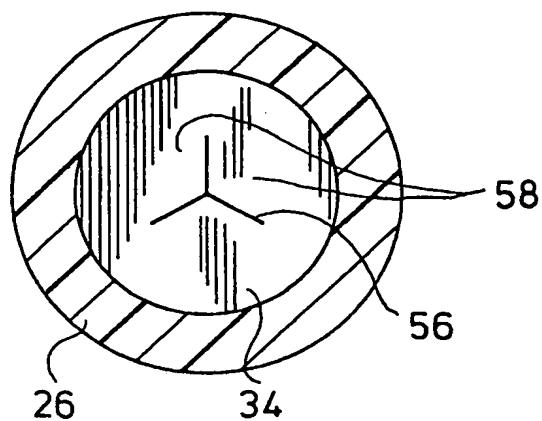


FIG. 1



2118440



SPECIFICATION

A self-sealing connector

5 The present invention relates to a connector for the connection of injection needles, catheters, flexible piping and the like, having a male connector part within an outer sleeve, and a female connector part, within an outer sleeve, and a female connector part, 10 that may be pushed into the sleeve, the female connector part having a connection face for forming a sealing join with the connection face of the male connector part. There is furthermore a system of locking elements on the inner face of the sleeve and 15 the outer face of the female connector part for keeping the parts of the connector in place in the coupled up condition.

A connector designed on these lines has been put forward in German Offenlegungsschrift specification 20 3,100,622, in the case of which the axial hole in the female connector part is shut off by a valve disk of elastic material as a shut-off valve whose normally shut slit or other opening is opened by the end of the outer cone face of the male connector part in the 25 coupled-up condition of the connector. In this coupled condition, the outer end of the outer cone face is pushed through the star-like slit opening in the valve disk, which is shut again automatically when the outer cone face is pulled back out of the disk, so 30 that, only that connector part (namely the female connector part) having the disk may be shut off, whereas the male connector part and the piece of flexible piping joined thereto is, by the nature of things, kept open, so that there may be a loss of 35 liquid out through the male connector part. Another point is that the open system part with the male connector part and the hole on it is likely to be contaminated by germs.

For stopping such contamination it is of little use 40 clamping the hose joined with the connector because the germs in the connector are likely to be swept through the connector by liquid and then make their way through the open hose to the body of the patient and be the cause of infection/inflammation.

45 Such contamination is more specially to be feared with patients undergoing continuous ambulant peritoneal dialysis (CAPD). As part of such treatment, a dialysis solution is run through a hose into the peritoneal cavity of the patient. For changing the 50 solution in the cavity, it is necessary for the hose to be shut down, this being done with the connector as noted hereinbefore. On opening up such a connector there is then likely to be contamination troubles which may even be responsible for peritonitis in the 55 patient. Although by using the connector of the sort noted the peritonitis rate, (which in the early days of CAPD was very high), was cut down, there are still some cases of the disease caused by the swelling of germs through a connector part in the uncoupled 60 condition.

A further prior art connector is to be seen in German Offenlegungsschrift specification 2,817,102, in which a well was made up of a female connector part with a hole through which

connector of German Offenlegungsschrift specification 3,100,622, the hole in the female connector part is shut off by a valve disk placed over and across its end and is opened by the end of a male connector part.

70 In view of the fact that this connector part may be used with other connector parts having different lengths of the cone face part, one special form of the connector had an axially sliding middle tube part for 75 guarding the opening of the valve disk, that is to say, the sliding tube part was in the form of an extension on the end of the male tube part so that the valve disk would be able to be opened even by male connector parts, that would not normally have been 80 long enough for opening the disk.

It will be seen from this that the female connector parts of the said German Offenlegungsschrift specifications 2,817,102 and 3,100,622 are shut off by a valve disk when not coupled up and in the coupled 85 condition are opened by the tip of the male connector part. On the other hand these German specifications make it clear that the male connector parts are generally open.

A further system, generally like the connector of 90 German Offenlegungsschrift specification 2,817,102, is to be seen in German Offenlegungsschrift specification 2,918,326. In this case as well there is a female connector part with a valve disk in it so that it might be opened by the end of a male connector part or a 95 steel needle. This being so, the observations made on the design of the said German Offenlegungsschrift specification 2,817,102 are true in this case as well.

It is for these reasons that one purpose of the 100 present invention is that of designing a male connector part whose opening or passageway is automatically shut off in the uncoupled condition of the connector and is opened in the coupled up condition.

105 For effecting this and further purposes that will become clear in the further account to be given herein, the central male tube part may be moved axially in the sleeve and at the inner or proximal end of the male tube part there is a valve member for 110 shutting off the passageway running through the connector, the valve being opened by the end of the male tube part when the tube part is moved axially.

In the first place one useful effect of the invention is that the male connector part is shut off by a valve 115 (preferably in the form of a disk) in the uncoupled condition. Such a valve disk is placed at the back of the inner connection piece or tube, that is slidingly positioned within the keeper part so that it may be moved axially. Because this is so, the passageway is 120 shut off by the valve part at a position at which it is not able to be touched.

For coupling up, the male connector part is run into the female connector part so that the faces of the inner and outer cone faces of the two connector 125 parts in question are force fitted or jammed against each other and give a liquid-tight sealing effect. The inside parts of the connector are made with such a size that firstly the valve disk is opened up by the end

thereof. Nextly, on screwing the female connector part in further within the male connector part, the axially sliding inner connector tube is pushed backwards thereby so that the further or second valve part is opened thereby, that is placed between this axially sliding part and the flexible piping or hose, and a liquid connection is produced through the connector, the two valves being opened.

On undoing the connector, the first step is pulling back the axially sliding tube clear of the second valve part, which, because of the force fit, goes on acting between the inner and outer cone faces. Then the force fit is overcome, that is to say, the male cone face is pulled back out of the female connector part, the first valve then being shut. It will be seen from this that in the uncoupled condition the two passageways, in the form of axial holes through the male and female parts of the connector, are shut off.

Because the passageways are shut off at the two ends, it is possible to make certain that there is in effect no change of germs making their way into the piping system. A further point is that the only parts that may be contaminated, if any, will be limited to a certain area of the face of the connector, which in any case may be readily disinfected with a disinfectant solution. Furthermore the sealing off of the pipe system from the outside will make certain that there is no change of the disinfectant running into the pipe system and then into the body of the patient. In fact the double self-sealing design of the valve system is responsible, as one of its effects, for a more readily undertaken disinfecting operation without any flow of disinfectant, which in large doses would be toxic, past the valve system having to be feared.

35 A further effect of the shutting of the valve means is naturally that there will be no loss of blood substitute or blood itself if the two connector parts are uncoupled by chance; that is to say the pipe system with the connector is made generally safer.

40 Further developments of the invention and useful effects thereof will be seen from the detailed account to be given and from the claims.

In order that the invention may be more readily understood, an embodiment thereof will now be described with reference to the accompanying drawings, in which:-

45 *Figure 1* is a lengthways section through a connector whose male and female parts are in the coupled condition;

50 *Figures 2 and 3* are radial-axial sections of the connector in two different positions thereof and on a larger scale than in *Figure 1*, but without the female connector part to make the Figure more straightforward;

55 *Figure 4* is a cross section and a surface view of the valve disk of the male connector part;

Figure 5 is a cross section through the male connector part on the line V-V of *Figure 1* but on a larger scale than this Figure; and

60 *Figure 6* is a cross section taken on the line VI-VI of *Figure 1*, again on a larger scale.

In *Figure 1* is a connector 10, which is made up of a male connector part 12 and a female connector part 14. The male connector part 12 has a central tube

therethrough and coming to an end at a nipple 20 (at the end of a plug 94), over which the end of a piece of flexible tubing such as part of a catheter may be slipped for making a join therewith. In the Figure the nipple 20 is cut short.

On generally the same lines the female connector part 14 has an axial passageway 22, the same running towards the back end of the female part and coming to an end at a second nipple 24 with which the end of a piece of hose or the like to be joined up with the connector may be coupled.

This female connector part 14 has a main tube part 26, whose front part 28 is stepped so that a front barrel 30 may be fitted thereto in such a way that at 80 a lower step 32 of the main tube part 26 a valve disk 34 may be kept in place therebetween stretching across the axial passageway 22. This valve disk 34 is kept up against the step 32 by the barrel 30.

The inner face of the barrel 30 is designed as the 85 inner cone face 36 of the female connector part 14, that has a form matching and mating with the male connector part 12 so as to give a firm force fit or jamming or wedging effect therewith. This inner cone face 36 is only present in the back part of the barrel 90 30, whereas the front part thereof is enlarged as a ring-like hollow 40 so that the barrel 30 is clear of the central tube part 16 at this position. Furthermore the outer face of this front part of the barrel 30 has a fastening means, more especially a screw thread or 95 the like, so that spaces 44 are formed.

Furthermore the main tube part 26, as part of a preferred form of the invention, has a ring-like groove 46 round it in its outer face to take up an O-ring 48. At the back end, that is to say the proximal 100 end of the female connector part, there is furthermore a flange 50 running out from the outer face of the main tube part 26. It is best for there to be a knurled grip part 52 to this to make handling of the connector simpler.

105 The valve disk 34, which will be seen from *Figure 1* to have the front part 54 of the central tube part 16 pushed therethrough, may be seen in the closed condition in *Figure 4*. The valve disk has a generally star-like cut or slit system 56 with arms running out

110 from the middle of the valve disk 34. On being pushed against by the front part 54 of the tube 16, this star-like cut system is opened out, the separate "petals" or cusps 58 thereof resting against the outer edge of the front tube part 54 and functioning as a seal therewith.

115 A further sealing effect is produced by the force fit between the outer cone face 38 and the inner cone face 36.

Further details of the female connector part may be in keeping with the account given in the said German Offenlegungsschrift specification 3,100,622, that is to be incorporated therein by reference.

The male connector part 12 has, as noted hereinbefore, a central tube part 16, that has an outer cone face 38 as its outer face, said cone face stretching generally from the front part 54 in a backward direction that is to say towards the proximal end of the male part 12. This outer cone face 38 and the inner cone face 36 matching it may for example be

hand the outer cone face 38 may have its place taken by a cylindrical part if the other part to which it is to be fittingly joined has the right form, for example in the form of a dish valve.

5 Next to this outer cone face 38 and to the back of the central part 16 there is a generally cylindrical part 60, that has a flange 62 at the back end thereof, and a cone face 64 running out to the back (i.e. proximally with respect to the male part) of it forming the end of 10 the central tube part 16. The central tube part 16 is able to be moved in an axial direction within an outer guide sleeve 66.

The outer sleeve 66 has as its main parts a front sleeve part 68, a middle sleeve part 70 and a back 15 sleeve part 72.

The inner diameter of the front (or distal) sleeve part is generally equal to the diameter of the main tube part 26 of the female connector part 14 so that the front sleeve part 68 may be slipped onto this 20 main tube part 26 of the connector and more specially pushed over and onto the O-ring 48 seated in same, the said O-ring 48 being squeezed together when this is done and is seated against the inner face of the front sleeve part 68. This gives a sealing 25 effect keeping out bacteria here as well.

The distance *a* (see Figure 2) between the end 74 of this front sleeve part 68 and the front tube part 54 of the central tube part 16, as measured in an axial direction, is so great that on pushing together the 30 two connector parts 12 and 14, even when they are not truly in line, the tube part 54 will only come into contact with the inner cone face 36. Furthermore the distance *a* is such that the tube part 54 is not able to be touched by the fingers by chance. This being so, 35 it is not possible for there to be contact with parts that might be contaminated in view of the size with which the parts of the system are made.

The front sleeve part 68 has, as a further useful development of the present invention, a means 76 40 on its inner wall for fixing the female connector part 14 in position, and which is designed for use with a mating means 42. More specifically, this means 76 is in the form of a screw thread. Next to this front sleeve part 68 there is the middle sleeve part 70, the 45 same running in a backward direction (proximally with respect to the male part) and having an inwardly running flange 78 therein. This flange 78 has an axial hole 80, whose diameter is generally the same as the diameter of the cylindrical part 60 of the 50 central tube part 16. The limiting wall of this axial hole 80 has an axial guiding function for the cylindrical part 60.

To the back of the flange 78 an inner face 86 of a sleeve part 84 has a diameter equal to the outer 55 diameter of the flange 62 on the central tube part 16 for the purpose of guiding the central tube part.

The back (proximal) side 82 of the flange 78 is used as a stop for the flange 62.

The cylindrical part 84 is stepped at 88, the step 60 running in an outward direction. The inner diameter of this part 84 of the back sleeve part 72 is the same as the diameter of a second valve disk 90, which is placed across the direction of liquid motion through the passageway. The outer edge 92 of the valve disk

of a plug 94 against the step 88.

This plug 94 is of generally cylindrical form, its outer diameter being the same as the inner diameter of the back sleeve part 72 so that it may be pushed 70 into this sleeve part and fixed in place therein by solvent welding. For the flow of the liquid it naturally has an axial hole 96. The nipple 20 is furthermore placed stretching centrally out to the back so that a flexible pipe or the like may be fixed thereon, as 75 noted earlier. The axial hole 96 becomes wider towards the valve disk 90 to take the form of a hollow or pocket 98 (see Figures 2 and 3), which is more especially coned in form so as to become wider, or it may be hemi-spherical. The inner diameter of this 80 hollow or pocket 98 at the end of this plug 94, that is to say right at the valve disk 90, is generally the same as the diameter of the axial hole 80. This front part (face 100) of the plug 94 keeps the valve disk 90 in place on the step 88, whereas the plug 94 itself is 85 fixed (as noted) by solvent welding to the back sleeve part 72.

As will be seen from Figures 2 and 3, the flange 62 in the uncoupled condition is on the back side 82 of the flange 78, whereas in the coupled condition it is 90 resting against the disk 90 that is kept in place by the end face 100 of the plug 94. More specially the distance between the back side 82 and the face of the valve disk 90 which is turned towards the central tube part 16 is of such a size that there will be no 95 pressure (caused by the central tube part 16) acting on the back side 82 or on the face of the valve disk 90.

An account will now be given of how the two connector parts 12 and 14 are put together.

100 Firstly the male connector part 12 is slipped onto the female connector part 14 until the tube part 54 of the middle tube part 16 comes up against the face of the valve disk 34. Because of its stiff elastic or elastomeric properties this valve disk firstly has the 105 effect of pushing the tube part 16 axially backwards and into the male part 12. Upon the two connector parts 12 and 14 being further moved the one into the other, the two valve disks 34 and 90 are opened up by the part 54 and by the cone face 64 and the two 110 star-like cut systems (see Figure 4) 56 are pushed open like cusps or petals 58 that are flared or folded outwards, the same naturally acting with an elastic force on the two end parts of the central tube part 16. At the same time or thereafter, as the two connector 115 parts are pushed one into the other, a force fit is produced between the inner cone face 36 and the outer cone face 38 while at the same time the stop of the flange comes up against the end face 100 or (more correctly) the part, placed thereagainst of the 120 valve disk 90.

It will be further seen from Figure 3 how the pocket 98 is used, that is to say to take up the folded back valve cusps in the opened condition of the disk 90 without such petals or segments running up against 125 or fouling the limit face of the pocket 98.

The connector parts 12 and 14 are kept in place in relation to each other by fixing means 42 and 76, that are best made in the form of screw threads, so that the two connector parts may be screwed together.

for the end 744 of the front sleeve part 68, and in this condition the two valve disks, are opened up as far as they will go and a force fit is produced between the inner and out cone faces.

5 If the design is such that the two connector parts have to be turned in relation to each other for locking the connector in the done up condition with such a screw thread, the central tube part is naturally turned as well about its own axis. It is then best for the 10 central tube part 16 and the inner part of the male connector part 12 to be designed to make this readily possible, that is to say by making the parts within the male connector part 12 round in cross section, where this is necessary to let turning motion take place.

15 To undo the two connector parts 12 and 14 the one part is pulled back away from the other. Because of the force fit between the inner cone face 36 and the outer cone face 38 the first thing to be effected when this is done is for the central tube part 16 to be axially 20 moved forwards and, if necessary, turned, the cone face 64 then being pulled clear out of the valve disk 90, whose "petals" or segments are automatically folded back into the shut position which they were in in the first place.

25 At the same time the flange 62 comes up against the back side 82 of the flange 78 so that the force fit between the inner cone face and the outer cone face comes to an end and at the same time the tube part 54 is pulled out of the second valve disk. In the end 30 the only step necessary is pulling the two connector parts 12 and 14 fully clear of each other, their passageways being shut off automatically by the valve disks therein so that there is no chance of loss of liquid therefrom or any contamination from

35 outside through the valve disks.

A further point to be noted is that the valve disks are made of an elastomeric material, as for example a rubber-like or silicone material. These valve parts, that are best made in the form of valve disks, do not 40 necesarily in all cases have to have the form of disks. It would naturally be possible for them to have the form of a dish. In this case it would not be necessary to have the inner cone face 38 for example, because in such a case the outer cone face would be taken up 45 within the dish valve and not only be pushed through the front part of this valve but be so moved that its outer cone face would be pushed against the inner wall of the dish valve with a force fit.

It is furthermore naturally possible for the cut or 50 slit system 56, that in the present working example is more specially in the form of a star, to have a completely different form. As a general point, it may be said that the elastic material used for making the valve parts will be so elastic that it will give a 55 complete and full sealing effect shutting off the passageway so that a certain amount of force is necessary for opening the cuts or slits in the valve disks.

For ruling out any chance of contamination as far 60 as possible on doing up the connector, the two parts 12 and 14 thereof may have a liquid disinfectant sprayed into them. Such a disinfectant that, in small amounts will not be any danger to the well-being of the patient, will be present in all the inside parts of

a disinfecting space may be present between the O-ring 48 and the force fit or connection point produced between the inner and the outer cone face 36 and 38. The disinfecting space, that is wetted with 70 disinfectant, is for this reason formed between the fastening means 42, that may be in the form of a bayonet or screw coupling and the hollow 49 and the passageway joining the two together.

For stopping any contamination in the space 102 75 between the valve disk 90 and the flange 78, it is best for it to be possible for the disinfectant in the connector to be able to make its way into such spaces as well and to make this possible it is best to have passageways 104 running between the central tube part 16 and the middle sleeve part 70 so that the disinfectant is able to get into the space 102.

In Figure 2 the reader will see a form of the connector in which there are a number of passageways 104 made in the middle sleeve part, the said 85 passageways running axially in the inner wall or sleeve part 68 and the back side 82 and along the axial hole 80. On the other hand, as will be seen from Figure 6, it is naturally possible for these passageways to be placed running in the central tube part 16, that is to say along the cylindrical part 60 and the flange 62. Further possible designs are to be seen in Figures 2 and 3 and in Figures 5 and 6.

This form of the invention will make certain that a second disinfectant space is formed in the space 102 95 on the valve disk 90 so that there is no chance of contamination at this point. There is in fact an even more complete sterilizing effect in such connectors.

The connectors in keeping with the present invention may be made of all materials as normally used 100 for such purposes, as for example polycarbonate, PTFE and the like and may well be made of glass-clear material. More specially they have a long working life and may be coupled and uncoupled a great number of times without wear or damage.

105 CLAIMS

1. A connector for liquid duct systems comprising a male connector part with an outer part thereof 110 formed as a sleeve, a female connector part designed to be pushed into said sleeve, said female connector part having a connection face designed for forming a seal on a connection face on the said male connector part, locking means on an inner face of the said sleeve and on an outer face of the female connector part, said locking means having the function of locking the said connector parts together with the said connection faces sealingly resting against each other, a central male tube part as part of 115 said male connector part, said tube part being able to be moved axially in the sleeve, a valve part at a proximal end of the tube part, said valve part being designed for shutting off a passageway running through the connector and being opened when the two parts of the connector are coupled together.

2. A connector as claimed in Claim 1 wherein the central tube part has a male connector cone face and a cylindrical part.

3. A connector as claimed in Claim 1 or Claim 2,

proximal end thereof which is slidably located in a space formed within said connector.

4. A connector as claimed in any of Claims 1 to 3, further having a cone face on said tube part proximally of said flange.

5. A connector as claimed in any of Claims 1 to 4, wherein a distal end of said tube part is axially within a distal end of said sleeve by a distance great enough for keeping the said distal end from being 10 touched.

6. A connector as claimed in any preceding Claim, wherein said sleeve between a middle and a proximal part thereof is formed with an inwardly running flange.

15 7. A connector as claimed in Claim 6, wherein the said inwardly running flange has an inner diameter equal to the outer diameter of a cylindrical part of said tube part within said flange.

8. A connector as claimed in Claim 6, comprising 20 a flange on said tube part and wherein said flange has a proximal side designed for acting as a stop for said flange formed on said tube part.

9. A connector as claimed in any of Claims 6 to 8, wherein next to the inwardly running flange and 25 proximally thereof said sleeve is cylindrical, an inner face of said cylindrical part being next to said flange on said tube part.

10. A connector as claimed in any of the preceding Claims, wherein said valve is a valve disk placed 30 between the middle of said sleeve and a proximal end thereof.

11. A connector as claimed in Claim 10, wherein the outer diameter of the valve disk is the same as 35 the inner diameter of the proximal sleeve end and is supported on a step therein.

12. A connector as claimed in Claim 10, further comprising a plug fitted in the proximal end of the sleeve, said plug having a pocket therein next to said disk and round a passageway through said plug.

40 13. A connector as claimed in Claim 12, wherein said pocket is of a form becoming wider towards said disk and is designed to take up folded back parts of same.

14. A connector as claimed in any of Claims 10 to 45 13, wherein the distance between a proximal side of said flange of said sleeve and the distal side of said valve disk is of such a size that the said distal side of the flange and the face of the valve disk are free of forces produced by said tube part.

50 15. A connector as claimed in Claim 12, wherein said plug has a ring part at one end thereof for pressing the valve disk against a step of said sleeve and at the same time acting as a stop for said flange on said tube part.

55 16. A connector as claimed in Claim 1, wherein said sleeve has a cylindrical proximal end part with a flange running inwards from an inner face thereof and said tube part has a cylindrical part with a flange formed thereon running outwards therefrom, said

60 connector having at least one axially running passageway running along a part selected from the group consisting of said cylindrical proximal end part, said flange thereon, said cylindrical part of said tube part and said flange thereon.

tially as herein described with reference to and as illustrated in the accompanying drawings.

Printed for Her Majesty's Stationery Office, by Croydon Printing Company Limited, Croydon, Surrey, 1983.
Published by The Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.